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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,084	06/14/2001	John Mamana	06920001AA	3811

7590 09/10/2002

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EXAMINER
PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/10/2002 6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/880,084	MAMANA, JOHN	
	Examiner	Art Unit	
	Patricia A Patten	1651	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *14-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

Applicant's election of Group I, Claims 1-13 in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 14-22 have been withdrawn from consideration as being drawn to a non-elected invention in Paper No. 5.

Claims 1-13 have been presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, and 7-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5, and 7-13 recite, or depend upon a claim which recites the term 'extract' without clearly defining what 'extract' the claims are referring to. Although the Instant specification has provided an example of one type of extract of green tea (p.3) it is not known what other extracts of green tea the claim encompasses. There are numerous extraction protocols known in the art, and each respective extraction protocol will necessarily produce distinct products which may have different effects when administered to an individual. For example, an organic solvent extract of green tea may not efficiently extract polyphenols which are intended as an active ingredient to promote weight loss. Thus, the meets and bounds of the term 'extract' is not clearly delineated and one of ordinary skill in the art may have trouble ascertaining exactly what other extracts besides the ones taught in the Instant Specification Applicants intend to claim. Limitation to the type of extract; i.e., alcoholic is necessary.

Claim 2 is indefinite in that the claim changes rather than limits claim 1 in the recitation 'in the form of' polynicotinate (for example). This is contradictory to what is known in the art since chromium is *not part of* polynicotinate or chloride for examples and thus, chromium cannot be 'in the form of' polynicotinate or chloride or picolinate. It is suggested that the claim be changed to read 'wherein the chromium additive is selected from the group consisting of chromium

polynicotinate, chromium amino acid chelate, chromium chloride, chromium picolinate and combinations thereof" in order to avoid confusion.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorsek (US 6,383,482 B1) in view of Eisenberg (1998).

Claims 1-13 are drawn to an appetite suppressant which comprises green tea, green tea leaf extract, a chromium additive wherein dependant claims limit the composition to include 5-hydroxytryptophan, and beta-hydroxy beta-methylbutyrate (HMB). Claims further include limitations to varying amounts of each respective constituent, wherein the green tea leaf extract contains about 50% catechin polyphenols and wherein the composition is in the form of a tablet, powder or capsule.

Gorsek (US 6,383,482 B1) taught a weight-loss composition which included

❒ green tea extract (20% polyphenols) (col 1, lines 53-58)

❒ chromium picolinate (claims 1 and 2), and

❒ 5-hydroxytryptophan (col. 2, lines 9-11 and claims 1 and 2).

Gorsek disclosed that the polyphenols of green tea extract were beneficial in inhibiting '..the enzyme that causes the breakdown of norepinephrine, thus causing an increase in metabolic rate' as well as beneficial in increasing fat metabolism (col.1, lines 53-58). Gorsek further disclosed that 5-hydroxytryptophan gave a feeling of satiation and calming effect which aided in weight loss (col.2, lines 5-7), and that chromium picolinate helped to metabolize fat and convert sugar into energy (col.2, lines 11-13). Gorsek specifically taught the composition in capsule form (col. 1, lines 37-38).

Gorsek did not specifically disclose wherein HMB or green tea was added to the composition, nor did he disclose the particular amounts of each constituent or wherein the green tea extract contained 50% polyphenols.

Eisenberg (1998) taught that HMB increased fat burning and muscle-building in athletes (see article under 'HMB').

Although neither reference taught the administration of green tea for weight-loss *per se*, Gorsek taught that the extracts from green tea contained polyphenols which aided in fat metabolism. Thus, this fat metabolizing property was intrinsic to green tea (the entire plant or leaf).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each was well known in the art for being administered as compositions for aiding weight-loss. This rejection is based on the well established proposition of patent law **that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients**, *In re Sussman,* 1943 C.D. 518. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore obvious.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Varying individual levels of constituents in a pharmaceutical preparation was considered routine experimental procedure at the time of the instant invention. One of ordinary skill in the art would have been motivated to have modified the proportions of active ingredients in the composition in order to enable the content of the preparation to be matched with the demands and needs of individuals which needed treatment.

Although Gorsek did not specifically teach wherein the green tea polyphenols were standardized to 50%, he did teach that it *was* the polyphenols which were the active ingredients relating to fat-burning. Thus, the ordinary artisan would have been motivated to have optimized

the percentage of polyphenols in the extract in order to have created a more potent weight-loss formulation. Optimization of result effective variables was considered routine in the art at the time the invention was made, and well within the purview of the ordinary artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CHRISTOPHER R. TATE
PRIMARY EXAMINER